

REMARKS

Favorable reconsideration of the subject application is respectfully requested in view of the above amendments and the following remarks. Prior to the present amendment, claims 1-40 were pending and under consideration. By the present amendment, claims 2-12, 14-17, 19-26, 28, 32, and 37 are canceled. Claims 1, 13, 18, 27, 29, 30, 31, 33, 34, 35, 36, 38, and 40 are amended to more specifically recite certain aspects of the invention. Support for these amendments may be found throughout the specification and claims as originally filed, and it is urged that the amendments do not constitute new matter. It should also be noted that the above amendments are not to be construed as acquiescence with regard to the Examiner's rejections and are made without prejudice to prosecution of any subject matter removed or modified by this amendment in a related divisional, continuation or continuation-in-part application.

Objections Under 37 C.F.R. § 1.75(c)

Claims 33-35 stand objected to under 37 C.F.R. § 1.75(c) for allegedly being in improper form due to a multiple dependent claim depending from another multiple dependent claim.

Applicants note that claim 33 has been amended to depend from independent claims 1 and 29, and claims 34 and 35 have been amended to each depend from a single claim. Accordingly, claims 33-35 are no longer multiple dependent claims depending from another multiple dependent claim. Applicants submit that this basis of objection is, therefore, obviated by the present amendment and respectfully request that it be withdrawn.

Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 1-32 and 36-40 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regards as the invention.

Claims 1 and 36 are allegedly indefinite in not providing a description of the structural cooperation between the sampler and the signal generator. Applicants respectfully traverse this basis of rejection and submit that the skilled artisan would clearly understand the

structural relationships between the sampler and signal generator. However, without acquiescence to this basis of rejection, claims 1, 29 and 36 have been amended to provide additional description of one embodiment such a structural relationship between these features of the claimed device. Applicants submit that the claims are clear, and meet the requirements of Section 112, second paragraph.

Claims 3, 4, 5, 6, 12, and 18 are allegedly indefinite for lacking antecedent basis for the phrases "said sampler washer," "said wash solution," "said sample collection pad," "said collection pad surface," and "the sample." Claims 3, 4, 5, 6, and 12 have been canceled without acquiescence to this basis of rejection, thereby obviating this basis of rejection. Claim 18 has been amended to depend from claim 31, which depends from claims 1 or 29, which each recite "a sample," and, therefore, provide proper antecedent basis for the phrase "the sample" in claim 18.

Claims 19, 22, and 40 are allegedly indefinite in reciting trademarked materials. Claims 19 and 22 have been canceled without acquiescence to this basis of rejection, thereby obviating this basis of rejection. Claim 40 has been amended to replace "Triton X-100" with one of its commonly known generic names, "polyethylene glycol P-1,1,3,3-tetramethylbutylphenyl ether" and to replace "Tween 20" with one of its commonly known generic names, "polysorbate 20," thereby obviating this basis of rejection.

Claims 23 and 25 are allegedly indefinite in not clearly reciting the location of elements of the claimed device. Claims 23 and 25 have been canceled without acquiescence to this basis of rejection, thereby obviating this basis of rejection.

Claim 30 is allegedly indefinite for not clearly describing the location of the reagent housing in relation to the sampler and signal generator. Applicants submit that the skilled artisan would clearly understand the location of the reagent housing. However, without acquiescence to this basis of rejection, claim 30 has been amended to recite one embodiment of the location of the reagent housing. Applicants respectfully submit that the claim is, thus, clear in its description of the claimed device.

Claim 36 is allegedly indefinite in reciting "the protein error family," which lacks antecedent basis. Applicants respectfully traverse this basis of rejection and submit that the

claim does not refer to “the protein error family” *per se* but, rather, refers to “a frequency shift dye of the protein error family,” which is defined throughout the specification as filed, including, e.g., on page 19, lines 19-24. Accordingly, it is respectfully submitted that no antecedent basis is required for the phrase “a frequency shift dye of the protein error family.”

Claims 37, 38, and 40 are allegedly indefinite for not being clear as to where the absorbent material, wetting agent, and signal generator are located in relation to the sampler and the signal generator. Applicants submit that the skilled artisan would clearly understand the location of these features of the invention. Nonetheless, without acquiescence to this basis of rejection, claim 37 has been canceled, and claims 36, 38 and 40 have been amended to more clearly describe one embodiment regarding potential locations of these features, thus satisfying the requirements of Section 112, second paragraph.

Applicants respectfully submit that the claims clearly describe the invention and request that these bases of rejection be withdrawn.

Rejections Under 35 U.S.C. § 102

Claims 1-27 stand rejected under 35 U.S.C. § 102(a) as allegedly anticipated by Carpenter *et al.* (WO 00/09016) and under 35 U.S.C. § 102(e) as allegedly being anticipated by Carpenter *et al.* (US 6,551,834). More specifically, the Action asserts that both of these references describe a self-contained sampling/testing device that comprises a sampler, a sample washer, and a signal generator comprising a dye. In addition, the Action alleges that these references teach that the device may further comprise additional features of the claimed invention.

Applicants respectfully traverse this basis of rejection and submit that the Carpenter references fail to anticipate the claimed invention. Without acquiescence to this basis of rejection and solely for the purpose of advancing prosecution of this case, claims 2-12, 14-17, and 19-26 have been canceled, and claim 1 has been amended to recite the additional feature that the sampler contains an absorbent pad at the surface of which is positioned a membrane to which the dye is attached either covalently or non covalently. Applicants note that this feature was previously recited in claim 28, which the Examiner recognized as being novel over the Carpenter

references. Applicants submit that since neither of the Carpenter references teach or suggest this feature of the claimed invention, they fail to anticipate the instant claims. Furthermore, Applicants note that the rejections based upon the Carpenter references are set forth under Section 102(a), and Applicants reserve the right to provide evidence establishing a date of invention prior to the critical dates of either Carpenter reference.

Claims 1, 6, 17, 23, and 29 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Stone. More specifically, the Action asserts that Stone teaches a self-contained sampling/testing device, which comprises a sampler in the form of a swab, with a test reagent impregnated into the swab. In addition, the Action asserts that the test reagent is a dye that reacts with the sample collected into the swab to form a detectable color change and notes that the device contains a breakable cartridge containing an activator or wetting solution for wetting the swab prior to sample collection and an additional cartridge containing the dye, which remains dry until a test is performed.

Applicants respectfully traverse this basis of rejection and submit that Stone fails to anticipate the claimed invention. Without acquiescence to this basis of rejection, claims 6, 17, and 23 have been canceled, and claim 1 has been amended as described above to recite the feature of claim 28 that the sampler contains an absorbent pad at the surface of which is positioned a membrane to which the dye is attached either covalently or non covalently. Applicants submit that Stone fails to teach or suggest this feature of the claimed invention and, therefore, clearly fails to anticipate claim 1. In addition, Applicants submit that Stone fails to teach or suggest a device wherein the dye is attached directly to the surface of an absorbent pad, as described in claim 29. Further, the device described by Stone comprises a swab impregnated with dye. Impregnation is simple absorption into a porous material, which is reversible, in contrast to covalent or non covalent binding to the surface of a material. Applicants note that the preparation of a device having dye bound to the surface of a membrane or absorbent pad is not only more technically challenging, but, importantly, prevents the device from leaving dye residues on a surface or sample being tested, which is critical for certain applications, such as, *e.g.*, testing food processing surfaces for the presence of bacteria. In addition, in the device of Stone, wherein the dye is impregnated into a porous material, visual reactions may be diluted or

not detectable due to substantial amounts of dye being located within the porous material as opposed to on the surface of the material, where visual reactions are most readily detectable. Accordingly, the feature of the claimed invention that the dye is attached either covalently or non covalently to a membrane or absorbent pad provides significant advantages over the device described by Stone. Furthermore, since this feature is not contemplated or described by Stone, Stone does not anticipate the claims.

Claims 1, 6, 13, 16, 24, 26, and 27 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Numa *et al.* The Action asserts that Numa *et al.* teaches a self-contained device for detecting proteins in which a sampling means is contacted with a surface to collect a sample, and the sample is then contacted with a reagent capable of forming a color upon reaction with a protein.

Applicants respectfully traverse this basis of rejection and submit that Numa fails to teach or suggest each element of the claimed invention, and, therefore, does not anticipate these claims. Without acquiescence to this basis of rejection, claims 6, 16, 24, and 26 have been canceled. In addition, claim 1 has been amended, as described above, to include the feature that the sampler contains an absorbent pad at the surface of which is positioned a membrane to which the dye is attached either covalently or non covalently. Indeed, Applicants note that the device of Numa does not include a dye pre-immobilized on the sampler at all. Applicants submit that Numa fails to teach or suggest this element of claim 1, and, accordingly, claims 1 and claims 13 and 27, dependent therefrom, are not anticipated by Numa.

Claims 1, 17, 20, 23, 29, 36, 37, and 39 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Keston. Specifically, the Action alleges that Keston teaches a protein indicator comprising a porous paper saturated with a protein detecting solution, which is used by dipping into a protein-containing liquid.

Applicants respectfully traverse this basis of rejection and submit that Keston also fails to teach the element that the dye is attached covalently or non covalently to the surface of an absorbent pad or a membrane, which is recited in each of remaining claims 1, 29, 36, and 39, which have been amended without acquiescence to this basis of rejection. Rather, as noted by the Examiner, the device described by Keston comprises a porous paper saturated with a protein

detecting solution. Furthermore, the device of Keston does not comprises a sampler, and, therefore, is limited in use to the testing of solutions, whereas the present invention comprises a sampler that may be used to collect target material from a sample. Accordingly, Keston fails to anticipate these claims. Claims 17, 20, 23, and 37 have been canceled without acquiescence, thereby obviating this basis of rejection as regards these claims.

In summary, Applicants submit that none of the cited references teach or suggest the presently claimed invention, which recites the feature that the sampler contains an absorbent pad or membrane to which the dye is attached either covalently or non covalently. Accordingly, none of these references anticipate the claimed invention. In light of these claim amendments and remarks, Applicants respectfully request that the rejections under Section 102 be withdrawn.

Rejections Under 35 U.S.C. § 103

Claims 29-32 and 36-40 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over either Carpenter reference in view of Keston. More specifically, the Examiner alleges that it would have been obvious to attach a signal generator dye directly to the absorbent sample collection pad of the sampler taught by Carpenter, since Keston teaches that a dye directly bonded to absorbent sample collection material allows for the instant reaction between any protein in a sample collected and the dye material.

Applicants respectfully traverse this basis of rejection and submit that these references, alone or in combination, fail to teach each element of the claimed invention. Without acquiescence, claims 32 and 37 have been canceled. Remaining claims 29-31, 36, and 38-40 all clearly recite the feature that the dye is either attached directly to the surface of an absorbent pad or to a membrane at the surface of an absorbent pad, either covalently or non covalently. In contrast to the Action's assertion, Applicants submit that Keston fails to teach a dye directly bonded to absorbent sample collection material. Indeed, neither Keston nor Carpenter teach a dye attached covalently or non covalently. As noted by the Examiner previously, Keston merely teaches a test paper made by saturating a porous paper with a solution containing an indicator. The indicator is not covalently or non covalently attached to the porous paper. Applicants further note that the preparation of a device having dye attached covalently or non covalently to

the surface of a membrane or absorbent pad is not only more technically challenging, but, importantly, prevents the device from leaving dye residues on a surface or sample being tested, which is critical for certain applications, such as, *e.g.*, testing food processing surfaces for the presence of bacteria. Accordingly, Applicants submit that since neither reference teaches or suggests a covalently or non covalently attached indicator, this combination of reference fails to render obvious the claimed invention.

Claim 28 stands rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over either Carpenter reference in view of Lee. More specifically, the Action alleges that it would have been obvious to form a sampler taught by Carpenter as an absorbent pad covered by a membrane to which the signal generator due is attached, similar to the test strip of Lee, since Lee teaches that this configuration in a body fluid collection device avoids too much dye-reacted target material from absorbing into the sampler.

Applicants respectfully traverse this basis of rejection and submit that these references, alone or in combination, fail to teach each element of the claimed invention, and, therefore, fail to render the invention obvious. Applicants note that claim 28 has been canceled and the features of claim 28 incorporated into amended claim 1. Applicants submit that neither of these references describe or suggest a membrane to which the signal generator is either covalently or non covalently attached. Rather, the test strip described by Lee comprises a dye impregnated membrane. As noted earlier, there are substantial and nonobvious differences between a membrane comprising impregnated with a dye and a membrane comprising a dye covalently or non covalently bound to its surface. For example, covalent or non covalent attachment of a dye or other signal generator to the membrane prevents the device from leaving dye residues on a surface or sample being tested, which is critical for certain applications, such as, *e.g.*, testing food processing surfaces for the presence of bacteria. Since Carpenter clearly fails to remedy this deficiency, this combination of references fails to render obvious the claimed invention.

In light of these amendments and remarks, Applicants submit that the claimed invention is nonobvious over the recited combinations of references and respectfully requests that these bases of rejection be withdrawn.

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The Commissioner is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

Applicants respectfully submit that all of the claims remaining in the application are now clearly allowable. Favorable consideration and a Notice of Allowance are earnestly solicited.

Respectfully submitted,

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